

## REMARKS

### Notice of Non-compliant Amendment

The Applicant's thank the Examiner for pointing out that the December 23, 2004 Applicant's Reply did not contain a complete listing of all claims. The Applicants respectfully ask the Examiner to replace all prior versions and listings of claims in the present application with the listing of claims currently provided. Claims 1-20 were canceled in a preliminary amendment mailed on December 19, 2000. Claims 21-30 and 33 are provisionally canceled because of an Examiner's restriction requirement, Claims 31, 32 and 34 are amended and Claims 35 and 36 are new.

### Restriction Requirement

Applicants provisionally elect to prosecute Examiner's Group IV, with traverse, and provisionally cancel claims 21-30 and 33. Applicants traverse concerns the propriety of dividing the claims based on the drug being coupled to the Clostridial neurotoxin being an extracellular drug or an intracellular drug. Applicants do not traverse (except reserving the right of rejoinder) the restriction of method (Groups I and II) and composition (Groups III and IV) claims on that basis alone.

The Examiner has indicated that method claims 21-30 (containing a single independent claim; claim 21) should be the subject of a restriction requirement. The Examiner acknowledges that the method of Group I (a method of treating a neurological dysfunction, said to be claimed in claims 21-27, 29 and 30) has the same purpose as the method of his Group II (a method of treating a neurological dysfunction). The only distinction that the Examiner makes is that the method of Group I allegedly makes use of a Clostridial neurotoxin coupled to an extracellular drug, and the method of Group II makes use of a Clostridial neurotoxin coupled to an intracellular drug. The composition claims (31-34) of Groups III and IV have been divided using the same rationale.

In order for a restriction requirement to be proper, two requirements must be met: first the alleged inventions must be shown to be separate and distinct. Secondly, the Examiner must demonstrate a serious burden unless restriction is made. See MPEP §803.

Concerning the first requirement, the Examiner states that Inventions I and II are independent and distinct because these Groups are "drawn to different methods with differing steps and differing goals and utilizing different reagents". Applicants disagree. Groups I and II encompass the same method using different reagents with possibly identical steps and identical goals. Applicants also note that embodiments of the method within each of the Examiner's Groups also employ different reagents. So there is really no logical distinction that can be made between embodiments in a single Group and embodiments within each Group.

The same can be said for the composition claims of Groups III and IV, whose only difference is in the moiety to be coupled to the neurotoxin. But this moiety will be different for embodiments within each Group as well.

Independent means there is no disclosed relationship between the two or more subjects disclosed. MPEP §802.1 Certainly these claims are related (a Clostridial neurotoxin relates all the claims), and Examiner has provided no argument or evidence to the contrary.

With regard to the second requirement, Applicants point out that the Examiner has indicated that Groups I and II (and Groups III and IV) fall within the same class and subclass – that is to say, a search of one “Group” is likely to result in art relating to the other “Group”. There is absolutely no evidence of any hardship, such as an increased search burden, to the Examiner.

#### CONCLUSION

Applicants believe that the new claims place the subject matter of Examiner’s Restriction Group III in condition for allowance, and respectfully request that the Examiner so indicate. The Examiner is invited to contact Applicants’ representative if it would be helpful in furthering the prosecution of this application.

Applicants authorize the use of Deposit Account No. 01-0885 for the payment of the petition fee under 37 CFR §1.17(m), and for the payment of any other fee that may be due in connection with this correspondence.

Respectfully submitted,



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